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Merging Quality Science With Supplement Research

A Strategic Plan For The Office of Dietary Supplements

The Office of Dietary Supplements (ODS) was established by the Dietary Supplement Health and Education Act of 1994 (DSHEA, Public Law 103-417) that amended the Federal Food, Drug, and Cosmetic Act "to establish standards with respect to dietary supplements." The ODS was placed at the National Institutes of Health (NIH) in the Office of the Director. Formal operations began in November 1995.

The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.

The purposes of the ODS within the NIH are:

- "…to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and
- …to promote the scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions."

The duties of the ODS are to:

- "conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;
- collect and compile the results of scientific research relating to dietary supplements, including data from foreign sources or the Office of Alternative Medicine;
- serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements;
- compile a database of scientific research on dietary supplements and individual nutrients; and
- coordinate funding relating to dietary supplements for the National Institutes of Health" (DSHEA, 1994).

Goal 1: Evaluate the role of dietary supplements in the prevention of disease and reduction of risk factors associated with disease.

Over 100 million Americans regularly use dietary supplements. Many supplement users report that they take dietary supplements to reduce the risk of disease or generally to promote health. Disease prevention research includes the identification of risk factors and interventions that prevent the occurrence of disease (or its progression, if detectable but asymptomatic). In a broader sense, it also includes analysis of the etiology and mechanisms of disease that may contribute basic knowledge applicable to future preventive interventions. As a unit within the NIH, the ODS must promote and support basic research that is likely to advance particular areas of science that may be relevant to clinical studies of efficacy and safety and specific health problems. To address Goal 1, the ODS sets the following objectives:

- Advance the understanding of the specific impact of nutrient and botanical supplements or their ingredients on immunocompetence particularly related to HIV/AIDS and infectious agents.
- Stimulate research on the potential roles of dietary supplements in reducing the risk and control of cancer*, particularly cancer of the breast, ovary, and prostate*.
- Evaluate the role of specific supplements in reducing the symptoms or pathology of coronary heart disease* and diabetes.
- Identify those dietary supplements that reduce the symptoms of, and possibly retard the progression of arthritis, including osteoarthritis.
- Introduce a cross-disciplinary initiative to study the interactions among diet, supplements, and physical activity in bone health and reducing the risk and progression of osteoporosis*.
- Develop strategies to evaluate the role of individual and multiple supplements to reduce the risk and progression of ocular disease, particularly cataracts* and macular degeneration.
- Foster the inclusion of research on the role of dietary supplements in federal initiatives to address the etiology, reduction, and health outcomes of obesity in the U.S. population.
- Examine whether dietary supplement use may influence the progression of oral diseases.

*Specific areas of scientific priority included in the DSHEA legislation.

Goal 2: Evaluate the role of dietary supplements in physical and mental health and in performance.

In 1996, the U.S. Surgeon General issued a report recommending that Americans increase their physical activity. In response to the Senate Appropriations Committee of the U.S. Congress, the Institute of Medicine, National Academy of Sciences prepared a report that detailed recommendations for mental health research. In keeping with these reports and the congressional mandate, ODS seeks to promote research on the scientific benefits and risks of dietary supplements in maintaining health and performance. The following are objectives to address Goal 2:

· Encourage research efforts to evaluate the relationships among dietary supplements and physical health and performance that includes the full range of age and population groups, hydration status, temperature regulation, environmental stress, and physical activity.

· Advance research on the role of dietary supplements in altering body composition and weight control.

· Advance research on the role of dietary supplements for increasing muscle strength, endurance, conditioning, and anaerobic power.

· Initiate research to identify and characterize the unique nutrient and caloric needs of persons with disabilities and elucidate potential roles for dietary supplements.

· Encourage research to determine the beneficial and detrimental effects of dietary supplements on mood, fatigue, stress, and psychological well-being.

· Promote further study of dietary supplements that have been demonstrated scientifically to enhance cognitive performance.

Goal 3: Explore the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.

The use of dietary supplements may influence biological systems or the physiological challenges to these systems during human development. One function of the ODS is to define areas of research focus and foster exploration of the biologic variables related to acute and chronic use of dietary supplements. The following objectives have been identified to carry out this goal:

· Investigate how dietary supplements may moderate specific processes of aging.

· Explore how the assimilation of dietary supplements varies with age-related physiologic changes.

· Advance the understanding of how dietary supplements may influence reproductive systems, birth defects*, and fetal development.

· Characterize the relationships among dietary supplements and basic cognitive processes, including attention, learning, and memory.

· Evaluate the role of individual supplements and supplement ingredients in the underlying pathophysiology of metabolic, endocrine, and gastrointestinal disorders, particularly those associated with drug abuse.

· Identify the changes in basic metabolic and physiologic processes that may occur with physical disabilities and potential roles for dietary supplements.

Goal 4: *Improve scientific methodology as related to the study of dietary supplements.*

Dietary supplement research is conducted across many scientific disciplines and supported by a wide array of methods. Key to enhancing progress in the field is the integration of research that accommodates the variety of supplements, supplement delivery systems, sites and mechanisms of action, and groups of individuals who take supplements. Scientific advancement with a particular supplement may hinge, therefore, on the development or refinement of appropriate and/or novel instrumentation or methods. To meet this goal, the ODS proposes the following objectives:

- Promote the identification and characterization of bioactive compounds in dietary supplements by delineating their mode of absorption, distribution, metabolism, mechanism of action, and excretion.
- Evaluate and develop animal and clinical methods for determining the efficacy and safety of dietary supplements.
- Develop new and validate existing epidemiological/ survey methods for assessing dietary supplement usage.
- Promote the collection of reliable and valid data on dietary supplement usage.
- Promote academic-government-industry partnerships to advance dietary supplement research and technology transfer.
- Develop model systems to predict and characterize the potential for adverse effects resulting from interactions among dietary supplements and nutrients, other supplements, and drugs.
- Identify and facilitate the development of new methods for characterizing supplements and their active components.
- Establish guidelines to delineate the combination of experimental methods necessary to demonstrate high confidence levels for efficacy and safety of dietary supplement use.

Goal 5: *Inform and educate scientists, health care providers, and the public about the benefits and risks of dietary supplements.*

The ODS Director was mandated by Congress [Public Law 103-417, Section 13.(a)] to serve in an advisory capacity to the Department of Health and Human Resources regarding "(A) dietary intake regulations; (B) the safety of dietary supplements, (C) claims characterizing the relationship between (i) dietary supplements; and (ii) (I) prevention of disease or other health-related conditions; and (II) maintenance of health; and (D) scientific issues arising in connection with the labeling and composition of dietary supplements." The Report of the Commission on Dietary Supplement Labels recommends that the ODS place greater emphasis on this advisory role. The ODS has included this mandate as a specific objective for achieving goal 5.

Since the ODS began in November 1995, the office has received over 1,200 calls or requests from the public for personal health care information about dietary supplements. An almost equal number of calls have been logged in the ODS from scientists and health care professionals. To assist these groups, the ODS will promote and support the development of scientifically valid information and educational materials on dietary supplements and individual nutrients through the objectives that follow:

- Serve as a key resource and adviser for policy makers about dietary supplements.*
- Develop and maintain a publicly accessible database of published, peer-reviewed, scientific literature on dietary supplements.*
- Develop and maintain a publicly accessible database of federally funded scientific research on dietary supplements.*
- Stimulate dialogue about dietary supplements among government agencies, academia, public advocacy groups, and industry.
- Facilitate the integration of scientific information on dietary supplements within standard and continuing education programs for health care providers.
- Promote training of scientific investigators in dietary supplements research, as well as effective communication of research results.
- Encourage the regular inclusion of dietary supplement intake information as part of a patient's medical history.
- Conduct a survey to assess the need for a public information system on dietary supplements.
- Evaluate and effectively communicate to the public the results of recent scientific research.

*Specific areas of scientific priority included in the DSHEA legislation.